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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,584	04/04/2001	Robert Akita	P1003R1C1D1	3718

7590 08/10/2004

Attn: Wendy M. Lee
Genentech; Inc.
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South San Francisco, CA 94080-4990

EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/825,584

Applicant(s)

AKITA ET AL.

Examiner

Christopher H Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-33 and 36-51 is/are rejected.
- 7) ☒ Claim(s) 34 and 35 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Re: Akita *et al*

Priority Date: 27 March 1996

1. The amendment filed 5/4/2004 is acknowledged and entered into the record. Accordingly, claims 1-21 are canceled without prejudice or disclaimer.
2. Claims 22-51 are pending and examined on the merits.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections Maintained - 35 USC § 103

4. The rejection of claims 22-33 and 36-51 under 35 USC § 103(a) as being obvious over Rajkumar *et al* in view of Orlandi *et al*, Cabilly *et al*, Boss *et al*, Robinson *et al*, Ward *et al*, Queen *et al*, and Huston *et al* is maintained for the reasons of record. Applicant primarily argues that the combination of the references do not teach, suggest or disclose the claimed invention. Applicant makes their point by arguing each reference individually. In particular, Applicant states that the primary reference does not teach an antibody that is effective in binding heregulin with ErbB3 nor do they disclose nucleic acid sequences that encode such an antibody. Applicant further argues to overcome the rejection by stating that each of the cited secondary references as a whole does not teach the deficiencies of the primary reference and states that they apply in general to any antibody and do not teach or suggest the functional limitations of the antibody taught in the instant invention. Lastly, Applicant argues that the combination of the reference do not teach, suggest or motivate one of skill in the art to obtain

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nucleic acid sequences that encode an antibody that affects heregulin induced formation of a complex of ErbB2-ErbB3, because such a complex was never suggested or motivated. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. In *re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In *re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the instant case, applicant argues that the references as combined do not teach the claimed invention because Rajkumar *et al* does not teach, suggest or motivate one of skill in the art to obtain the nucleic acid sequence encoding the antibody. However, it is the combination of the references that make obvious the instant invention. Although it is not taught in Rajkumar *et al*, others, such as Orlandi *et al* taught that it was routine to obtain Vh and VI nucleic acid sequences via PCR amplification from an antibody. Thus, when Rajkumar *et al* teaches the antibody, and others such as Orlandi *et al* teach methods of obtaining the nucleic acid sequence of the antibody, one of ordinary skill in the art would find it obvious to obtain the nucleic acid sequence of the antibody taught by Rajkumar *et al*. Thus it was through the combination of the primary reference with the general teachings of the secondary references that one of skill in the art would have found obvious and motivation for obtaining the nucleic acid sequences from the antibody of Rajkumar *et al*. Further, one of skill would have expected a reasonable amount of success in doing so because

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Orlandi *et al*, for example has already taught that it was possible to extract and obtain such a nucleic acid sequence through PCR amplification.

Applicant's other argument pertains to functional limitations of the antibody, more specifically, that the instant invention must be capable of binding to ErbB3 and reduces heregulin induced formation of ErbB2-ErbB3 protein complex. A case of *prima facie* obviousness cannot be rebutted by merely recognizing additional advantages or latent properties present in the prior art. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In *re Wiseman*, 596 F.2d 1019, 201 USPQ 658 (CCPA 1979). In the instant case, Rajkumar *et al* taught an antibody that was capable of binding to ErbB3 and because the claims are drawn to a nucleic acid sequence or a product *per se*, the functional limitation of the nucleic acid does not read any patentable weight into the claims, because for these properties are view as inherent properties of the claimed antibody. Furthermore, because the patent office does not have the facilities to determine such functional distinctions between the claimed invention and that of the prior art, in the absence of factual evidence to the contrary, the antibody taught by Rajkumar *et al* would have the same function of reducing heregulin induced formation of ErbB2-ErbB3 protein complex formation.

Therefore, the rejection under 35 USC 103(a) as being obvious is maintained.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
6. Claims 22-33, and 36-51 are rejected. Claims 34 and 35 are free of the prior art and are objected to because they are dependent of a claim that is rejected. Thus no claims are allowed.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

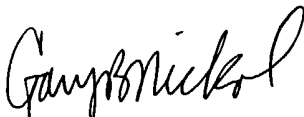
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
Art Unit 1642
August 6, 2004


GARY NICKOL
PRIMARY EXAMINER